

National Organic Program

Subpart A, C, D, E, and sections 205.102 through 205.105

Subpart A - Definitions

§ 205.1 Meaning of words. For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand.

§ 205.2 Terms defined.

Accreditation. A determination made by the Secretary that authorizes a private, foreign, or State entity to conduct certification activities as a certifying agent under this part.

Act. The Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 et seq.).

Action level. The limit at or above which the Food and Drug Administration will take legal action against a product to remove it from the market. Action levels are based on unavoidability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable.

Administrator. The Administrator for the Agricultural Marketing Service, United States Department of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

Agricultural inputs. All substances or materials used in the production or handling of organic agricultural products.

Agricultural product. Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

Allowed synthetic. A substance that is included on the National List of synthetic substances allowed for use in organic production or handling.

Agricultural Marketing Service (AMS). The Agricultural Marketing Service of the United States Department of Agriculture.

Animal drug. Any drug as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 321), that is intended for use in livestock, including any drug intended for use in livestock feed but not including such livestock feed.

Annual seedling. A plant grown from seed that will complete its life cycle or produce a harvestable yield within the same crop year or season in which it was planted.

Area of operation. The types of operations: crops, livestock, wild-crop harvesting or handling, or any combination thereof that a certifying agent may be accredited to certify under this part.

Audit trail. Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as "100 percent organic," the organic ingredients of any agricultural product labeled as "organic" or "made with organic (specified ingredients)" or the organic ingredients of any agricultural product containing less

than 70 percent organic ingredients identified as organic in an ingredients statement.

Biodegradable. Subject to biological decomposition into simpler biochemical or chemical components.

Biologics. All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

Breeder stock. Female livestock whose offspring may be incorporated into an organic operation at the time of their birth.

Buffer zone. An area located between a certified production operation or portion of a production operation and an adjacent land area that is not maintained under organic management. A buffer zone must be sufficient in size or other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact by prohibited substances applied to adjacent land areas with an area that is part of a certified operation.

Bulk. The presentation to consumers at retail sale of an agricultural product in unpackaged, loose form, enabling the consumer to determine the individual pieces, amount, or volume of the product purchased.

Certification or certified. A determination made by a certifying agent that a production or handling operation is in compliance with the Act and the regulations in this part, which is documented by a certificate of organic operation.

Certified operation. A crop or livestock production, wild-crop harvesting or handling operation, or portion of such operation that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Act and the regulations in this part.

Certifying agent. Any entity accredited by the Secretary as a certifying agent for the purpose of certifying a production or handling operation as a certified production or handling operation.

Certifying agent's operation. All sites, facilities, personnel, and records used by a certifying agent to conduct certification activities under the Act and the regulations in this part.

Claims. Oral, written, implied, or symbolic representations, statements, or advertising or other forms of communication presented to the public or buyers of agricultural products that relate to the organic certification process or the term, "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or, in the case of agricultural products containing less than 70 percent organic ingredients, the term, "organic," on the ingredients panel.

Commercially available. The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

Commingling. Physical contact between unpackaged organically produced and nonorganically produced agricultural products during production, processing, transportation, storage or handling, other than during the manufacture of a multiingredient product containing both types of ingredients.

Compost. The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131F and 170F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131 F and 170 F for 15 days, during which time, the materials must be turned a minimum of five times.

Control. Any method that reduces or limits damage by populations of pests, weeds, or diseases to levels that do not significantly reduce productivity.

Crop. A plant or part of a plant intended to be marketed as an agricultural product or fed to livestock.

Crop residues. The plant parts remaining in a field after the harvest of a crop, which include stalks, stems, leaves, roots, and weeds.

Crop rotation. The practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years so that crops of the same species or family are not grown repeatedly without interruption on the same field. Perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation.

Crop year. That normal growing season for a crop as determined by the Secretary.

Cultivation. Digging up or cutting the soil to prepare a seed bed; control weeds; aerate the soil; or work organic matter, crop residues, or fertilizers into the soil.

Cultural methods. Methods used to enhance crop health and prevent weed, pest, or disease problems without the use of substances; examples include the selection of appropriate varieties and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames, or wind breaks.

Detectable residue. The amount or presence of chemical residue or sample component that can be reliably observed or found in the sample matrix by current approved analytical methodology.

Disease vectors. Plants or animals that harbor or transmit disease organisms or pathogens which may attack crops or livestock.

Drift. The physical movement of prohibited substances from the intended target site onto an organic operation or portion thereof.

Emergency pest or disease treatment program. A mandatory program authorized by a Federal, State, or

local agency for the purpose of controlling or eradicating a pest or disease.

Employee. Any person providing paid or volunteer services for a certifying agent.

Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

Feed. Edible materials which are consumed by livestock for their nutritional value. Feed may be concentrates (grains) or roughages (hay, silage, fodder). The term, "feed," encompasses all agricultural commodities, including pasture ingested by livestock for nutritional purposes.

Feed additive. A substance added to feed in micro quantities to fulfill a specific nutritional need; i.e., essential nutrients in the form of amino acids, vitamins, and minerals.

Feed Supplement. A combination of feed nutrients added to livestock feed to improve the nutrient balance or performance of the total ration and intended to be:

- (1) Diluted with other feeds when fed to livestock;
- (2) Offered free choice with other parts of the ration if separately available; or
- (3) Further diluted and mixed to produce a complete feed.

Fertilizer. A single or blended substance containing one or more recognized plant nutrient(s) which is used primarily for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth.

Field. An area of land identified as a discrete unit within a production operation.

Forage. Vegetative material in a fresh, dried, or ensiled state (pasture, hay, or silage), which is fed to livestock.

Governmental entity. Any domestic government, tribal government, or foreign governmental subdivision providing certification services.

Handle. To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

Handler. Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their own production, except such term shall not include final retailers of agricultural products that do not process agricultural products.

Handling operation. Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

Immediate family. The spouse, minor children, or blood relatives who reside in the immediate household of a certifying agent or an employee, inspector, contractor, or

other personnel of the certifying agent. For the purpose of this part, the interest of a spouse, minor child, or blood relative who is a resident of the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent shall be considered to be an interest of the certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent.

Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).

Information panel. That part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes (e.g., irregular shape with one usable surface).

Ingredient. Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.

Ingredients statement. The list of ingredients contained in a product shown in their common and usual names in the descending order of predominance.

Inspector. Any person retained or used by a certifying agent to conduct inspections of certification applicants or certified production or handling operations.

Inspection. The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.

Label. A display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed, or graphic material which contains only information about the weight of the product.

Labeling. All written, printed, or graphic material accompanying an agricultural product at any time or written, printed, or graphic material about the agricultural product displayed at retail stores about the product.

Livestock. Any cattle, sheep, goat, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; wild or domesticated game; or other nonplant life, except such term shall not include aquatic animals or bees for the production of food, fiber, feed, or other agricultural-based consumer products.

Lot. Any number of containers which contain an agricultural product of the same kind located in the same conveyance, warehouse, or packing house and which are available for inspection at the same time.

Manure. Feces, urine, other excrement, and bedding produced by livestock that has not been composted.

Market information. Any written, printed, audiovisual, or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs, distributed, broadcast, or made available outside of retail outlets that are used to assist in the sale or promotion of a product.

Mulch. Any nonsynthetic material, such as wood chips, leaves, or straw, or any synthetic material included on the National List for such use, such as newspaper or plastic that serves to suppress weed growth, moderate soil temperature, or conserve soil moisture.

Narrow range oils. Petroleum derivatives, predominately of paraffinic and naphthenic fractions with 50 percent boiling point (10 mm Hg) between 415F and 440F.

National List. A list of allowed and prohibited substances as provided for in the Act.

National Organic Program (NOP). The program authorized by the Act for the purpose of implementing its provisions.

National Organic Standards Board (NOSB). A board established by the Secretary under 7 U.S.C. 6518 to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of the National Organic Program.

Natural resources of the operation. The physical, hydrological, and biological features of a production operation, including soil, water, wetlands, woodlands, and wildlife.

Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

Nonsynthetic (natural). A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act.

Nontoxic. Not known to cause any adverse physiological effects in animals, plants, humans, or the environment.

Nonretail container. Any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.

Organic. A labeling term that refers to an agricultural product produced in accordance with the Act and the regulations in this part.

Organic matter. The remains, residues, or waste products of any organism.

Organic production. A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

Organic system plan. A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling described in the Act and the regulations in subpart C of this part.

Pasture. Land used for livestock grazing that is managed to provide feed value and maintain or improve soil, water, and vegetative resources.

Peer review panel. A panel of individuals who have expertise in organic production and handling methods and certification procedures and who are appointed by the Administrator to assist in evaluating applicants for accreditation as certifying agents.

Person. An individual, partnership, corporation, association, cooperative, or other entity.

Pesticide. Any substance which alone, in chemical combination, or in any formulation with one or more substances is defined as a pesticide in section 2(u) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(u) *et seq.*)

Petition. A request to amend the National List that is submitted by any person in accordance with this part.

Planting stock. Any plant or plant tissue other than annual seedlings but including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation.

Practice standard. The guidelines and requirements through which a production or handling operation implements a required component of its production or handling organic system plan. A practice standard includes a series of allowed and prohibited actions, materials, and conditions to establish a minimum level performance for planning, conducting, and maintaining a function, such as livestock health care or facility pest management, essential to an organic operation.

Principal display panel. That part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale.

Private entity. Any domestic or foreign nongovernmental for-profit or not-for-profit organization providing certification services.

Processing. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

Processing aid.

(1) substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form;

(2) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and

(3) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and

does not have any technical or functional effect in that food.

Producer. A person who engages in the business of growing or producing food, fiber, feed, and other agricultural-based consumer products.

Production lot number/identifier. Identification of a product based on the production sequence of the product showing the date, time, and place of production used for quality control purposes.

Prohibited substance. A substance the use of which in any aspect of organic production or handling is prohibited or not provided for in the Act or the regulations of this part.

Records. Any information in written, visual, or electronic form that documents the activities undertaken by a producer, handler, or certifying agent to comply with the Act and regulations in this part.

Residue testing. An official or validated analytical procedure that detects, identifies, and measures the presence of chemical substances, their metabolites, or degradation products in or on raw or processed agricultural products.

Responsibly connected. Any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant or a recipient of certification or accreditation.

Retail food establishment. A restaurant; delicatessen; bakery; grocery store; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat-food.

Routine use of parasiticide. The regular, planned, or periodic use of parasiticides.

Secretary. The Secretary of Agriculture or a representative to whom authority has been delegated to act in the Secretary's stead.

Sewage sludge. A solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

Slaughter stock. Any animal that is intended to be slaughtered for consumption by humans or other animals.

Split operation. An operation that produces or handles both organic and nonorganic agricultural products.

Soil and water quality. Observable indicators of the physical, chemical, or biological condition of soil and water, including the presence of environmental contaminants.

State. Any of the several States of the United States of America, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

State certifying agent. A certifying agent accredited by the Secretary under the National Organic Program and operated by the State for the purposes of certifying organic production and handling operations in the State.

State organic program (SOP). A State program that meets the requirements of section 6506 of the Act, is approved by the Secretary, and is designed to ensure that a

product that is sold or labeled as organically produced under the Act is produced and handled using organic methods.

State organic program's governing State official. The chief executive official of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of the State, such official who administers a State organic certification program.

Synthetic. A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Tolerance. The maximum legal level of a pesticide chemical residue in or on a raw or processed agricultural commodity or processed food.

Transplant. A seedling which has been removed from its original place of production, transported, and replanted.

Unavoidable residual environmental contamination (UREC). Background levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances.

Wild crop. Any plant or portion of a plant that is collected or harvested from a site that is not maintained under cultivation or other agricultural management.

Sections 205.102-105

§ 205.102 Use of the term, "organic."

Any agricultural product that is sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be:

(a) Produced in accordance with the requirements specified in § 205.101 or §§ 205.202 through 205.207 or §§ 205.236 through 205.239 and all other applicable requirements of part 205; and

(b) Handled in accordance with the requirements specified in § 205.101 or §§ 205.270 through 205.272 and all other applicable requirements of this part 205.

§ 205.103 Recordkeeping by certified operations.

(a) A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

(b) Such records must:

(1) Be adapted to the particular business that the certified operation is conducting;

(2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited;

(3) Be maintained for not less than 5 years beyond their creation; and

(4) Be sufficient to demonstrate compliance with the Act and the regulations in this part.

(c) The certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent.

§ 205.104 [Reserved]

§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:

(a) Synthetic substances and ingredients, except as provided in § 205.601 or § 205.603;

(b) Nonsynthetic substances prohibited in § 205.602 or § 205.604;

(c) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;

(d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in § 205.606;

(e) Excluded methods, except for vaccines, *Provided*, That, the vaccines are approved in accordance with § 205.600(a);

(f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and

(g) Sewage sludge.

Subpart C - Organic Production and Handling Requirements

§ 205.200 General.

The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must comply with the applicable provisions of this subpart. Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality.

§ 205.201 Organic production and handling system plan.

(a) The producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:

(1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;

(2) A list of each substance to be used as a production or handling input, indicating its composition,

source, location(s) where it will be used, and documentation of commercial availability, as applicable;

(3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;

(4) A description of the recordkeeping system implemented to comply with the requirements established in § 205.103;

(5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and

(6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

(b) A producer may substitute a plan prepared to meet the requirements of another Federal, State, or local government regulatory program for the organic system plan: *Provided*, That, the submitted plan meets all the requirements of this subpart.

§ 205.202 Land requirements.

Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as "organic," must:

(a) Have been managed in accordance with the provisions of §§ 205.203 through 205.206;

(b) Have had no prohibited substances, as listed in § 205.105, applied to it for a period of 3 years immediately preceding harvest of the crop; and

(c) Have distinct, defined boundaries and buffer zones such as runoff diversions to prevent the unintended application of a prohibited substance to the crop or contact with a prohibited substance applied to adjoining land that is not under organic management.

§ 205.203 Soil fertility and crop nutrient management practice standard.

(a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.

(b) The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.

(c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include:

(1) Raw animal manure, which must be composted unless it is:

(i) Applied to land used for a crop not intended for human consumption;

(ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible

portion has direct contact with the soil surface or soil particles; or

(iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;

(2) Composted plant and animal materials produced through a process that

(i) established an initial C:N ratio of between 25:1 and 40:1; and

(ii) maintained a temperature of between 131 F and 170 F for 3 days using an in-vessel or static aerated pile system; or

(iii) maintained a temperature of between 131F and 170F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.

(3) Uncomposted plant materials.

(d) A producer may manage crop nutrients and soil fertility to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances by applying:

(1) A crop nutrient or soil amendment included on the National List of synthetic substances allowed for use in organic crop production;

(2) A mined substance of low solubility;

(3) A mined substance of high solubility, *Provided*, That, the substance is used in compliance with the conditions established on the National List of nonsynthetic materials prohibited for crop production;

(4) Ash obtained from the burning of a plant or animal material, except as prohibited in paragraph (e) of this section: *Provided*, That, the material burned has not been treated or combined with a prohibited substance or the ash is not included on the National List of nonsynthetic substances prohibited for use in organic crop production; and

(5) A plant or animal material that has been chemically altered by a manufacturing process: *Provided*, That, the material is included on the National List of synthetic substances allowed for use in organic crop production established in § 205.601.

(e) The producer must not use:

(1) Any fertilizer or composted plant and animal material that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic crop production;

(2) Sewage sludge (biosolids) as defined in 40 CFR Part 503; and

(3) Burning as a means of disposal for crop residues produced on the operation: *Except*, That, burning may be used to suppress the spread of disease or to stimulate seed germination.

§ 205.204 Seeds and planting stock practice standard.

(a) The producer must use organically grown seeds, annual seedlings, and planting stock: *Except*, That,

(1) Nonorganically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not

commercially available, *Except*, That, organically produced seed must be used for the production of edible sprouts;

(2) Nonorganically produced seeds and planting stock that have been treated with a substance included on the National List of synthetic substances allowed for use in organic crop production may be used to produce an organic crop when an equivalent organically produced or untreated variety is not commercially available;

(3) Nonorganically produced annual seedlings may be used to produce an organic crop when a temporary variance has been granted in accordance with § 205.290(a)(2);

(4) Nonorganically produced planting stock to be used to produce a perennial crop may be sold, labeled, or represented as organically produced only after the planting stock has been maintained under a system of organic management for a period of no less than 1 year; and

(5) Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the materials is a requirement of Federal or State phytosanitary regulations.

(b) [Reserved]

§ 205.205 Crop rotation practice standard.

The producer must implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation:

- (a) Maintain or improve soil organic matter content;
- (b) Provide for pest management in annual and perennial crops;
- (c) Manage deficient or excess plant nutrients; and
- (d) Provide erosion control.

§ 205.206 Crop pest, weed, and disease management practice standard.

(a) The producer must use management practices to prevent crop pests, weeds, and diseases including but not limited to:

(1) Crop rotation and soil and crop nutrient management practices, as provided for in §§ 205.203 and 205.205;

(2) Sanitation measures to remove disease vectors, weed seeds, and habitat for pest organisms; and

(3) Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases.

(b) Pest problems may be controlled through mechanical or physical methods including but not limited to:

- (1) Augmentation or introduction of predators or parasites of the pest species;
- (2) Development of habitat for natural enemies of pests;

(3) Nonsynthetic controls such as lures, traps, and repellents.

(c) Weed problems may be controlled through:

- (1) Mulching with fully biodegradable materials;
- (2) Mowing;
- (3) Livestock grazing;
- (4) Hand weeding and mechanical cultivation;
- (5) Flame, heat, or electrical means; or
- (6) Plastic or other synthetic mulches: *Provided*,

That, they are removed from the field at the end of the growing or harvest season.

(d) Disease problems may be controlled through:

- (1) Management practices which suppress the spread of disease organisms; or
- (2) Application of nonsynthetic biological, botanical, or mineral inputs.

(e) When the practices provided for in paragraphs (a) through (d) of this section are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a substance included on the National List of synthetic substances allowed for use in organic crop production may be applied to prevent, suppress, or control pests, weeds, or diseases: *Provided*, That, the conditions for using the substance are documented in the organic system plan.

(f) The producer must not use lumber treated with arsenate or other prohibited materials for new installations or replacement purposes in contact with soil or livestock.

§ 205.207 Wild-crop harvesting practice standard.

(a) A wild crop that is intended to be sold, labeled, or represented as organic must be harvested from a designated area that has had no prohibited substance, as set forth in § 205.105, applied to it for a period of 3 years immediately preceding the harvest of the wild crop.

(b) A wild crop must be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

§§ 205.208 - 205.235 [Reserved]

§ 205.236 Origin of livestock.

(a) Livestock products that are to be sold, labeled, or represented as organic must be from livestock under continuous organic management from the last third of gestation or hatching: *Except*, That,

(1) *Poultry*. Poultry or edible poultry products must be from poultry that has been under continuous organic management beginning no later than the second day of life;

(2) *Dairy animals*. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic, *Except*, That, when an entire, distinct herd is converted to organic production, the producer may:

(i) For the first 9 months of the year, provide a minimum of 80-percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements; and

(ii) Provide feed in compliance with § 205.237 for the final 3 months.

(iii) Once an entire, distinct herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation.

(3) *Breeder stock.* Livestock used as breeder stock may be brought from a nonorganic operation onto an organic operation at any time: *Provided*, That, if such livestock are gestating and the offspring are to be raised as organic livestock, the breeder stock must be brought onto the facility no later than the last third of gestation.

(b) The following are prohibited:

(1) Livestock or edible livestock products that are removed from an organic operation and subsequently managed on a nonorganic operation may be not sold, labeled, or represented as organically produced.

(2) Breeder or dairy stock that has not been under continuous organic management since the last third of gestation may not be sold, labeled, or represented as organic slaughter stock.

(c) The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed animals and edible and nonedible animal products produced on the operation.

§ 205.237 Livestock feed.

(a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and, if applicable, organically handled: *Except*, That, nonsynthetic substances and synthetic substances allowed under § 205.603 may be used as feed additives and supplements.

(b) The producer of an organic operation must not:

(1) Use animal drugs, including hormones, to promote growth;

(2) Provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life;

(3) Feed plastic pellets for roughage;

(4) Feed formulas containing urea or manure;

(5) Feed mammalian or poultry slaughter by-products to mammals or poultry; or

(6) Use feed, feed additives, and feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.

§ 205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:

(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;

(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);

(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

(4) Provision of conditions which allow for exercise, freedom of movement, and reduction of stress appropriate to the species;

(5) Performance of physical alterations as needed to promote the animal's welfare and in a manner that minimizes pain and stress; and

(6) Administration of vaccines and other veterinary biologics.

(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: *Provided*, That, such medications are allowed under § 205.603. Parasiticides allowed under § 205.603 may be used on

(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and

(2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

(c) The producer of an organic livestock operation must not:

(1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.603, or any substance that contains a nonsynthetic substance prohibited in § 205.604.

(2) Administer any animal drug, other than vaccinations, in the absence of illness;

(3) Administer hormones for growth promotion;

(4) Administer synthetic parasiticides on a routine basis;

(5) Administer synthetic parasiticides to slaughter stock;

(6) Administer animal drugs in violation of the Federal Food, Drug, and Cosmetic Act; or

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.

§ 205.239 Livestock living conditions.

(a) The producer of an organic livestock operation must establish and maintain livestock living conditions which accommodate the health and natural behavior of animals, including:

(1) Access to the outdoors, shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment;

(2) Access to pasture for ruminants;

(3) Appropriate clean, dry bedding. If the bedding is typically consumed by the animal species, it must comply with the feed requirements of § 205.237;

- (4) Shelter designed to allow for:
 - (i) Natural maintenance, comfort behaviors, and opportunity to exercise;
 - (ii) Temperature level, ventilation, and air circulation suitable to the species; and
 - (iii) Reduction of potential for livestock injury;
- (b) The producer of an organic livestock operation may provide temporary confinement for an animal because of:
 - (1) Inclement weather;
 - (2) The animal's stage of production;
 - (3) Conditions under which the health, safety, or well being of the animal could be jeopardized; or
 - (4) Risk to soil or water quality.
- (c) The producer of an organic livestock operation must manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes recycling of nutrients.

§§ 205.240 - 205.269 [Reserved]

§ 205.270 Organic handling requirements.

- (a) Mechanical or biological methods, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.
- (b) Nonagricultural substances allowed under § 205.605 and nonorganically produced agricultural products allowed under § 205.606 may be used:
 - (1) In or on a processed agricultural product intended to be sold, labeled, or represented as "organic," pursuant to § 205.301(b), if not commercially available in organic form.
 - (2) In or on a processed agricultural product intended to be sold, labeled, or represented as "made with organic (specified ingredients or food group(s))," pursuant to § 205.301(c).
- (c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or in or on any ingredients labeled as organic:
 - (1) Practices prohibited under paragraphs (e) and (f) of § 205.105.
 - (2) A volatile synthetic solvent or other synthetic processing aid not allowed under § 205.605, *Except*, That, nonorganic ingredients in products labeled "made with organic (specified ingredients or food group(s))" are not subject to this requirement.

§ 205.271 Facility pest management practice standard.

- (a) The producer or handler of an organic facility must use management practices to prevent pests, including but not limited to:
 - (1) Removal of pest habitat, food sources, and breeding areas;
 - (2) Prevention of access to handling facilities; and
 - (3) Management of environmental factors, such as temperature, light, humidity, atmosphere, and air circulation, to prevent pest reproduction.
- (b) Pests may be controlled through:
 - (1) Mechanical or physical controls including but not limited to traps, light, or sound; or
 - (2) Lures and repellents using nonsynthetic or synthetic substances consistent with the National List.
- (c) If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control pests, a nonsynthetic or synthetic substance consistent with the National List may be applied.
- (d) If the practices provided for in paragraphs (a), (b), and (c) of this section are not effective to prevent or control facility pests, a synthetic substance not on the National List may be applied, *Provided*, That, the handler and certifying agent agree on the substance, method of application, and measures to be taken to prevent contact of the organically produced products or ingredients with the substance used.
- (e) The handler of an organic handling operation who applies a nonsynthetic or synthetic substance to prevent or control pests must update the operation's organic handling plan to reflect the use of such substances and methods of application. The updated organic plan must include a list of all measures taken to prevent contact of the organically produced products or ingredients with the substance used.
- (f) Notwithstanding the practices provided for in paragraphs (a), (b), (c), and (d) of this section, a handler may otherwise use substances to prevent or control pests as required by Federal, State, or local laws and regulations, *Provided*, That, measures are taken to prevent contact of the organically produced products or ingredients with the substance used.

§ 205.272 Commingling and contact with prohibited substance prevention practice standard.

- (a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.
- (b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:
 - (1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;
 - (2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

§§ 205.273 - 205.289 [Reserved]

§ 205.290 Temporary variances.

(a) Temporary variances from the requirements in §§ 205.203 through 205.207, 205.236 through 205.239, and 205.270 through 205.272 may be established by the Administrator for the following reasons:

(1) Natural disasters declared by the Secretary;

(2) Damage caused by drought, wind, flood, excessive moisture, hail, tornado, earthquake, fire, or other business interruption; and

(3) Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling.

(b) A State organic program's governing State official or certifying agent may recommend in writing to the Administrator that a temporary variance from a standard set forth in subpart C of this part for organic production or handling operations be established: *Provided*, That, such variance is based on one or more of the reasons listed in paragraph (a) of this section.

(c) The Administrator will provide written notification to certifying agents upon establishment of a temporary variance applicable to the certifying agent's certified production or handling operations and specify the period of time it shall remain in effect, subject to extension as the Administrator deems necessary.

(d) A certifying agent, upon notification from the Administrator of the establishment of a temporary variance, must notify each production or handling operation it certifies to which the temporary variance applies.

(e) Temporary variances will not be granted for any practice, material, or procedure prohibited under § 205.105.

§§ 205.291-205.299 [Reserved]

Subpart D - Labels, Labeling, and Market Information
§ 205.300 Use of the term, "organic."

(a) The term, "organic," may only be used on labels and in labeling of raw or processed agricultural products, including ingredients, that have been produced and handled in accordance with the regulations in this part. The term, "organic," may not be used in a product name to modify a nonorganic ingredient in the product.

(b) Products for export, produced and certified to foreign national organic standards or foreign contract buyer requirements, may be labeled in accordance with the organic labeling requirements of the receiving country or contract buyer: *Provided*, That, the shipping containers and shipping documents meet the labeling requirements specified in § 205.307(c).

(c) Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part and labeled pursuant to this subpart D.

(d) Livestock feeds produced in accordance with the requirements of this part must be labeled in accordance with the requirements of § 205.306.

§ 205.301 Product composition.

(a) *Products sold, labeled, or represented as "100 percent organic."* A raw or processed agricultural product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) 100 percent organically produced ingredients. If labeled as organically produced, such product must be labeled pursuant to § 205.303.

(b) *Products sold, labeled, or represented as "organic."* A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to § 205.303.

(c) *Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))."* Multiingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients or food group(s))" must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (1), (2), and (3) of § 205.301(f). Nonorganic ingredients may be produced without regard to paragraphs (4), (5), (6), and (7) of § 205.301(f). If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to § 205.304.

(d) *Products with less than 70 percent organically produced ingredients.* The organic ingredients in multiingredient agricultural product containing less than 70 percent organically produced ingredients (by weight or fluid volume, excluding water and salt) must be produced and handled pursuant to requirements in subpart C of this part. The nonorganic ingredients may be produced and handled without regard to the requirements of this part. Multiingredient agricultural product containing less than 70 percent organically produced ingredients may represent the organic nature of the product only as provided in § 205.305.

(e) *Livestock feed:*

(1) A raw or processed livestock feed product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) not less than 100 percent organically produced raw or processed agricultural product.

(2) A raw or processed livestock feed product sold, labeled, or represented as "organic" must be produced in conformance with § 205.237.

(f) All products labeled as "100 percent organic" or "organic" and all ingredients identified as "organic" in the ingredient statement of any product must not:

(1) Be produced using excluded methods, pursuant to § 201.105(e);

(2) Be produced using sewage sludge, pursuant to § 201.105(f);

(3) Be processed using ionizing radiation, pursuant to § 201.105(g);

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: *Except*, That, products labeled as "100 percent organic," if processed, must be processed using organically produced processing aids;

(5) Contain sulfites, nitrates, or nitrites added during the production or handling process, *Except*, That, wine containing added sulfites may be labeled "made with organic grapes";

(6) Be produced using nonorganic ingredients when organic ingredients are available; or

(7) Include organic and nonorganic forms of the same ingredient.

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or that include organic ingredients must be calculated by:

(1) Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product.

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.

(b) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number.

(c) The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage.

§ 205.303 Packaged products labeled "100 percent organic" or "organic."

(a) Agricultural products in packages described in § 205.301(a) and (b) may display, on the principal display panel, information panel, and any other panel of the package and on any labeling or market information concerning the product, the following:

(1) The term, "100 percent organic" or "organic," as applicable, to modify the name of the product;

(2) For products labeled "organic," the percentage of organic ingredients in the product; (The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.)

(3) The term, "organic," to identify the organic ingredients in multiingredient products labeled "100 percent organic";

(4) The USDA seal; and/or

(5) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the finished product and any other certifying agent which certified production or handling operations producing raw organic product or organic ingredients used in the finished product: *Provided*, That, the handler producing the finished product maintain records, pursuant to this part, verifying organic certification of the operations producing such ingredients, and: *Provided further*, That, such seals or marks are not individually displayed more prominently than the USDA seal.

(b) Agricultural products in packages described in § 205.301(a) and (b) must:

(1) For products labeled "organic," identify each organic ingredient in the ingredient statement with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by * * *," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product and may display the business address, Internet address, or telephone number of the certifying agent in such label.

§ 205.304 Packaged products labeled "made with organic (specified ingredients or food group(s))."

(a) Agricultural products in packages described in § 205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product:

(1) The statement:

(i) "Made with organic (specified ingredients)": *Provided*, That, the statement does not list more than three organically produced ingredients; or

(ii) "Made with organic (specified food groups)": *Provided*, That, the statement does not list more than three of the following food groups: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables or processed milk products; and, *Provided Further*, That, all ingredients of each listed food group in the product must be organically produced; and

(iii) Which appears in letters that do not exceed one-half the size of the largest type size on the panel and which appears in its entirety in the same type size, style, and color without highlighting.

(2) The percentage of organic ingredients in the product. The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.

(3) The seal, logo, or other identifying mark of the certifying agent that certified the handler of the finished product.

(b) Agricultural products in packages described in § 205.301(c) must:

(1) In the ingredient statement, identify each organic ingredient with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by * * *," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product: *Except*, That, the business address, Internet address, or telephone number of the certifying agent may be included in such label.

(c) Agricultural products in packages described in § 205.301(c) must not display the USDA seal.

§ 205.305 Multiingredient packaged products with less than 70 percent organically produced ingredients.

(a) An agricultural product with less than 70 percent organically produced ingredients may only identify the organic content of the product by:

(1) Identifying each organically produced ingredient in the ingredient statement with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced, and

(2) If the organically produced ingredients are identified in the ingredient statement, displaying the product's percentage of organic contents on the information panel.

(b) Agricultural products with less than 70 percent organically produced ingredients must not display:

(1) The USDA seal; and

(2) Any certifying agent seal, logo, or other identifying mark which represents organic certification of a product or product ingredients.

§ 205.306 Labeling of livestock feed.

(a) Livestock feed products described in § 205.301(e)(1) and (e)(2) may display on any package panel the following terms:

(1) The statement, "100 percent organic" or "organic," as applicable, to modify the name of the feed product;

(2) The USDA seal;

(3) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the raw or processed

organic ingredients used in the finished product, *Provided*, That, such seals or marks are not displayed more prominently than the USDA seal;

(4) The word, "organic," or an asterisk or other reference mark which is defined on the package to identify ingredients that are organically produced. Water or salt included as ingredients cannot be identified as organic.

(b) Livestock feed products described in § 205.301(e)(1) and (e)(2) must:

(1) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by * * *," or similar phrase, display the name of the certifying agent that certified the handler of the finished product. The business address, Internet address, or telephone number of the certifying agent may be included in such label.

(2) Comply with other Federal agency or State feed labeling requirements as applicable.

§ 205.307 Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

(a) Nonretail containers used only to ship or store raw or processed agricultural product labeled as containing organic ingredients may display the following terms or marks:

(1) The name and contact information of the certifying agent which certified the handler which assembled the final product;

(2) Identification of the product as organic;

(3) Special handling instructions needed to maintain the organic integrity of the product;

(4) The USDA seal;

(5) The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product.

(b) Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable.

(c) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled in accordance with any shipping container labeling requirements of the foreign country of destination or the container labeling specifications of a foreign contract buyer: *Provided*, That, the shipping containers and shipping documents accompanying such organic products are clearly marked "For Export Only" and: *Provided further*, That, proof of such container marking and export must be maintained by the handler in accordance with recordkeeping requirements for exempt and excluded operations under § 205.101.

§ 205.308 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as "100 percent organic" or "organic."

(a) Agricultural products in other than packaged form may use the term, "100 percent organic" or "organic," as applicable, to modify the name of the product in retail display, labeling, and display containers: *Provided*, That, the term, "organic," is used to identify the organic ingredients listed in the ingredient statement.

(b) If the product is prepared in a certified facility, the retail display, labeling, and display containers may use:

(1) The USDA seal; and

(2) The seal, logo, or other identifying mark of the certifying agent that certified the production or handling operation producing the finished product and any other certifying agent which certified operations producing raw organic product or organic ingredients used in the finished product: *Provided*, That, such seals or marks are not individually displayed more prominently than the USDA seal.

§ 205.309 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as "made with organic (specified ingredients or food group(s))."

(a) Agricultural products in other than packaged form containing between 70 and 95 percent organically produced ingredients may use the phrase, "made with organic (specified ingredients or food group(s))," to modify the name of the product in retail display, labeling, and display containers.

(1) Such statement must not list more than three organic ingredients or food groups, and

(2) In any such display of the product's ingredient statement, the organic ingredients are identified as "organic."

(b) If prepared in a certified facility, such agricultural products labeled as "made with organic (specified ingredients or food group(s))" in retail displays, display containers, and market information may display the certifying agent's seal, logo, or other identifying mark.

§ 205.310 Agricultural products produced on an exempt or excluded operation.

(a) An agricultural product organically produced or handled on an exempt or excluded operation must not:

(1) Display the USDA seal or any certifying agent's seal or other identifying mark which represents the exempt or excluded operation as a certified organic operation, or

(2) Be represented as a certified organic product or certified organic ingredient to any buyer.

(b) An agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multiingredient product produced by the exempt or excluded operation. Such product or ingredient must not be identified or represented as "organic" in a product processed by others.

(c) Such product is subject to requirements specified in paragraph (a) of § 205.300, and paragraphs (f)(1) through (f)(7) of § 205.301.

§ 205.311 USDA Seal.

(a) The USDA seal described in paragraphs (b) and (c) of this section may be used only for raw or processed agricultural products described in paragraphs (a), (b), (e)(1), and (e)(2) of § 205.301.

(b) The USDA seal must replicate the form and design of the example in figure 1 and must be printed legibly and conspicuously:

(1) On a white background with a brown outer circle and with the term, "USDA," in green overlaying a white upper semicircle and with the term, "organic," in white overlaying the green lower half circle; or

(2) On a white or transparent background with black outer circle and black "USDA" on a white or transparent upper half of the circle with a contrasting white or transparent "organic" on the black lower half circle.

(3) The green or black lower half circle may have four light lines running from left to right and disappearing at the point on the right horizon to resemble a cultivated field.



§§ 205.312-205.399 [Reserved]

Subpart E - Certification

§ 205.400 General requirements for certification.

A person seeking to receive or maintain organic certification under the regulations in this part must:

(a) Comply with the Act and applicable organic production and handling regulations of this part;

(b) Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent as provided for in § 205.200;

(c) Permit on-site inspections with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices by the certifying agent as provided for in § 205.403;

(d) Maintain all records applicable to the organic operation for not less than 5 years beyond their creation

and allow authorized representatives of the Secretary, the applicable State organic program's governing State official, and the certifying agent access to such records during normal business hours for review and copying to determine compliance with the Act and the regulations in this part, as provided for in § 205.104;

(e) Submit the applicable fees charged by the certifying agent; and

(f) Immediately notify the certifying agent concerning any:

(1) Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation; and

(2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.

§ 205.401 Application for Certification.

A person seeking certification of a production or handling operation under this subpart must submit an application for certification to a certifying agent. The application must include the following information:

(a) An organic production or handling system plan, as required in § 205.200;

(b) The name of the person completing the application; the applicant's business name, address, and telephone number; and, when the applicant is a corporation, the name, address, and telephone number of the person authorized to act on the applicant's behalf;

(c) The name(s) of any organic certifying agent(s) to which application has previously been made; the year(s) of application; the outcome of the application(s) submission, including, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification; and a description of the actions taken by the applicant to correct the noncompliances noted in the notification of noncompliance, including evidence of such correction; and

(d) Other information necessary to determine compliance with the Act and the regulations in this part.

§ 205.402 Review of application.

(a) Upon acceptance of an application for certification, a certifying agent must:

(1) Review the application to ensure completeness pursuant to § 205.401;

(2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;

(3) Verify that an applicant who previously applied to another certifying agent and received a notification of noncompliance or denial of certification, pursuant to § 205.405, has submitted documentation to support the correction of any noncompliances identified in the notification of noncompliance or denial of certification, as required in § 205.405(e); and

(4) Schedule an on-site inspection of the operation to determine whether the applicant qualifies for certification if the review of application materials reveals

that the production or handling operation may be in compliance with the applicable requirements of subpart C of this part.

(b) The certifying agent shall within a reasonable time:

(1) Review the application materials received and communicate its findings to the applicant;

(2) Provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed; and

(3) Provide the applicant with a copy of the test results for any samples taken by an inspector.

(c) The applicant may withdraw its application at any time. An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance will not be issued a notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

§ 205.403 On-site inspections.

(a) *On-site inspections.*

(1) A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.

(2) (i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.

(ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.

(iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official.

(b) *Scheduling.*

(1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: *Except*, That, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.

(2) All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the

applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.

(c) *Verification of information.* The on-site inspection of an operation must verify:

(1) The operation's compliance or capability to comply with the Act and the regulations in this part;

(2) That the information, including the organic production or handling system plan, provided in accordance with §§ 205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;

(3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.

(d) *Exit interview.* The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.

(e) *Documents to the inspected operation.*

(1) At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken.

(2) A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.

§ 205.404 Granting certification.

(a) Within a reasonable time after completion of the initial on-site inspection, a certifying agent must review the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant. If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the requirements of this part and that the applicant is able to conduct operations in accordance with the plan, the agent shall grant certification. The certification may include requirements for the correction of minor noncompliances within a specified time period as a condition of continued certification.

(b) The certifying agent must issue a certificate of organic operation which specifies the:

(1) Name and address of the certified operation;

(2) Effective date of certification;

(3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and

(4) Name, address, and telephone number of the certifying agent.

(c) Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic program's governing State official, or the Administrator.

§ 205.405 Denial of certification.

(a) When the certifying agent has reason to believe, based on a review of the information specified in § 205.402 or § 205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant. When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification. The notification of noncompliance shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) Upon receipt of such notification of noncompliance, the applicant may:

(1) Correct noncompliances and submit a description of the corrective actions taken with supporting documentation to the certifying agent;

(2) Correct noncompliances and submit a new application to another certifying agent: *Provided*, That, the applicant must include a complete application, the notification of noncompliance received from the first certifying agent, and a description of the corrective actions taken with supporting documentation; or

(3) Submit written information to the issuing certifying agent to rebut the noncompliance described in the notification of noncompliance.

(c) After issuance of a notification of noncompliance, the certifying agent must:

(1) Evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal, conduct an on-site inspection if necessary, and

(i) When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, issue the applicant an approval of certification pursuant to § 205.404; or

(ii) When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, issue the applicant a written notice of denial of certification.

(2) Issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance.

(3) Provide notice of approval or denial to the Administrator, pursuant to § 205.501(a)(14).

(d) A notice of denial of certification must state the reason(s) for denial and the applicant's right to:

(1) Reapply for certification pursuant to §§ 205.401 and 205.405(e);

(2) Request mediation pursuant to § 205.663 or, if applicable, pursuant to a State organic program; or

(3) File an appeal of the denial of certification pursuant to § 205.681 or, if applicable, pursuant to a State organic program.

(e) An applicant for certification who has received a written notification of noncompliance or a written notice of denial of certification may apply for certification again at any time with any certifying agent, in accordance with §§ 205.401 and 205.405(e). When such applicant submits a new application to a certifying agent other than the agent who issued the notification of noncompliance or notice of denial of certification, the applicant for certification must include a copy of the notification of noncompliance or notice of denial of certification and a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliance.

(f) A certifying agent who receives a new application for certification, which includes a notification of noncompliance or a notice of denial of certification, must treat the application as a new application and begin a new application process pursuant to § 205.402.

(g) Notwithstanding paragraph (a) of this section, if a certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant's operation or its compliance with the certification requirements pursuant to this part, the certifying agent may deny certification pursuant to paragraph (c)(1)(ii) of this section without first issuing a notification of noncompliance.

§ 205.406 Continuation of certification.

(a) To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:

(1) An updated organic production or handling system plan which includes:

(i) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic system plan during the previous year; and

(ii) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to § 205.200;

(2) Any additions to or deletions from the information required pursuant to § 205.401(b);

(3) An update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification; and

(4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

(b) Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site

inspection of the certified operation pursuant to § 205.403: *Except*, That, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months: *Provided*, That, the annual on-site inspection, required pursuant to § 205.403, is conducted within the first 6 months following the certified operation's scheduled date of annual update.

(c) If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in § 205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with § 205.662.

(d) If the certifying agent determines that the certified operation is complying with the Act and the regulations in this part and that any of the information specified on the certificate of organic operation has changed, the certifying agent must issue an updated certificate of organic operation pursuant to § 205.404(b).

§§ 205.407-205.499 [Reserved]